SEP 09 2009

K092841 p. 1 of 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: August 28, 2009

Submitter:

Name:	Blazejewski MEDI-TECH GmbH
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Product:

Trade Name:	Spinal Foraminoscope
Classification:	Class II
Common Name:	Foraminoscope
Classification Name:	Arthroscope

Predicate Devices:

- Yeung Endoscopic Spine System, Richard Wolf Medical Instruments Corp., K973405
- Spine Scope, Model 2180, Clarus Medical, LLC., K011454
- Pollux Arthroscopes, Pollux Endoscopy, Inc., K953484

Device Description: The Spinal Foraminoscope for lumbar access is an optical and fiberoptic-based rigid endoscope provided with a 2.8 or 3.7 mm working channel and two 1.5-mm irrigation channels and allowing insertion of 2.8-mm or 3.5-mm hand-held instruments.

The Spinal Foraminoscope for cervical access is a fiberoptic-based rigid endoscope which shares the same design. It is provided with a 2.2-mm working and irrigation channel, has a 3.6-mm outer diameter and allows insertion of 2.0-mm hand-held instruments.

The Spinal Foraminoscope may be attached to standard fiberoptic light sources and Storz, Olympus, Wolf and ACM cameras and video adapters.

Intended Use: The Spinal Foraminoscope is intended for endoscopic visualization of the lumbar and cervical spine.

Performance Data: Testing was performed to support substantial equivalence to the predicate device. The Spinal Foraminoscope met all specified design and performance requirements.

Sterilization The Spinal Foraminoscope is offered non-sterile for autoclave steam sterilization.

Conclusion: Based upon the product technical information provided, intended use and performance information provided in this premarket notification, as well as similarity to legally marketed devices, Blazejewski MEDI-TECH GmbH considers the Spinal Foraminoscope to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 09 2009

Blazejewski Medi-Tech GmbH
% Business Support International
Ms. Angelika Scherp
Regulatory Affairs Consultant
Amstel 320-I
Amsterdam 1017AP
Netherlands

Re: K082841
Trade/Device Name: Spinal Foraminoscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 28, 2009
Received: August 31, 2009

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082841 p.1 of 1

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Spinal Foraminoscope

Indications for Use: The Spinal Foraminoscope for lumbar access is indicated for endoscopic visualization in the lumbar region. The Spinal Foraminoscope for cervical access is indicated for visual inspection of the cervical spinal nerve roots and surrounding tissue.

Prescription Use X AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082841